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UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

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CHARLOTTE WEATHERFORD, Plaintiff, vs. BOSTON SCIENTIFIC CORPORATION, Defendant.	Case No.: 3:22-cv-00337 **ORIGINAL COMPLAINT** **JURY TRIAL DEMANDED**

I. INTRODUCTION

1. Plaintiff, by her undersigned counsel, brings this Complaint against Defendant Boston Scientific Corporation ("Defendant" or "BSC") related to the design, manufacture, marketing, distribution and sale of Defendant's Obtryx Pelvic Mesh Product implanted in Plaintiff. Plaintiff makes the following allegations based upon her individual personal knowledge as to her own acts, and upon information and belief, as well as upon her attorneys' investigative efforts as to Defendant's actions and misconduct, and alleges as follows:

II. PARTIES

2. Plaintiff Charlotte Weatherford is presently a citizen and resident of the State of California but at the time of implantation of the Obtryx device was a resident of Nevada. Plaintiff has suffered and continues to suffer significant injury as a result of Defendant's products and the

conduct alleged herein.

5. Defendant Boston Scientific Corporation is a Massachusetts corporation with its principal place of business in Massachusetts. At all times material hereto, Boston Scientific was engaged in the business of developing, manufacturing, licensing, promoting, marketing, distributing, testing, warranting and/or selling in interstate commerce throughout the United States, including Nevada, either directly or indirectly, its medical devices intended to treat stress urinary incontinence and/or pelvic organ prolapse, including the Obtryx product that was implanted into Plaintiff.

III. JURISDICTION AND VENUE

3. This Court has jurisdiction pursuant to 28 U.S.C. § 1332, as complete diversity exists between Plaintiff and Defendant, and the amount in controversy exceeds $75,000. Defendant is subject to in personam jurisdiction in this court, and venue is proper within this district pursuant to 28 U.S.C. § 1391, as a substantial number of the events, actions, or omissions giving rise to the Plaintiff's claims occurred in this district. At all times relevant to this matter, Defendant conducted substantial business in this district. Defendant did (and does) business within the state of Nevada and has had substantial, continuous, and systematic contacts with the state of Nevada, has consented to jurisdiction in the state of Nevada, and/or committed a tort in whole or in part in the state of Nevada, against Plaintiff herein, as more fully set forth below.

IV. FACTUAL BACKGROUND

The Pelvic Mesh Products

4. At all times relevant herein, Defendant was engaged in the business of developing, designing, licensing, manufacturing, distributing, marketing, packaging, labeling, advertising delivering, selling and introducing into interstate commerce, including within the United States and within the State of Nevada, either directly or indirectly through third parties or related entities, a line of pelvic mesh products (the "Pelvic Mesh Products"), including the Obtryx mesh product, the device implanted into Plaintiff. The Obtryx product was designed primarily for the purpose of treating stress urinary incontinence. All references herein to Pelvic Mesh Products includes the Obtryx pelvic mesh product.

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5. Stress urinary incontinence ("SUI") is a type of incontinence characterized by leakage of urine during moments of physical stress, such as coughing, laughing, or sneezing. Although inconvenient, SUI is not life-threatening. At all relevant times, the Obtryx was intended to be used, and for Plaintiff was used, to treat stress urinary incontinence.

6. Surgical mesh is a medical device that is generally used to repair weakened or damaged tissue. This is the type of mesh used in Defendant's Pelvic Mesh Products, including the Obtryx pelvic mesh product at issue in this case. In urogynecologic procedures, surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse (POP) or to support the urethra to treat SUI. Most pelvic mesh products, including the Obtryx, are comprised of non-absorbable, synthetic, monofilament polypropylene mesh. Defendant's Pelvic Mesh Products, including the Obtryx pelvic mesh products, were and are specifically promoted to physicians and patients as an innovative, minimally invasive procedure with minimal local tissue reactions, minimal tissue trauma, and minimal pain while correcting SUI and POP.

7. Pelvic mesh products used for the surgical management of SUI in women are primarily three different designs: the transobturator sling, the retropubic sling, and the single-incision or "mini sling." The Obtryx sling is a transobturator sling.

8. Prior the implantation of the Obtryx pelvic mesh product at issue in this claim, Defendant sought and obtained Food and Drug Administration ("FDA") approval to market the Obtryx under Section 510(k) of the Medical Device Amendment to the Food, Drug and Cosmetics Act. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. No formal review for safety or efficacy is required.

9. In 1996, the FDA cleared the first pelvic mesh products for use in the treatment of SUI. These products include products manufactured, marketed, and distributed by Defendant. These products were and are approved by the FDA under the abbreviated 510(k) approval process. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted with regard to these pelvic mesh products, including the Obtryx pelvic mesh product at issue in this case.

10. Despite claims that polypropylene mesh is inert, the scientific evidence shows that this material as implanted in Plaintiff and others is biologically incompatible with human tissue,

and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendant's Pelvic Mesh Products.

11. This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, and causes chronic inflammation of the pelvic tissue, shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response, and chronic pain. It also can cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the mesh. Certain information was available in the medical literature regarding the dangers of polypropylene mesh and manufacturers should have been aware of this literature.

1. Shrinkage and bacteria lead to an evolving process and increased erosion (Klinge U. Eur J Surg 1998; 164:965, Jacquetin B. Int Urogyn J 2009; 20:893, Tunn R. Ultrasound Obstetrics Gynecol 2007; 29:449).
2. Polypropylene mesh has long been known to shrink (Klinge U. Eur J Surg 1998; 164:965, Jacquetin B. Int Urogyn J 2009; 20:893, Tunn R. Ultrasound Obstetrics Gynecol 2007; 29:449). By 1998, polypropylene mesh was known to shrink 30-50%. This was subsequently confirmed in 2007 (Klinge U. Eur J Surg 1998; 164:965, Jacquetin B. Int Urogyn J 2009; 20:893, Tunn R. Ultrasound Obstetrics Gynecol 2007; 29:449). Predominate infection/inflammation was noted in 2007 in explanted polypropylene samples (Yahi Y. Int Urogyn J 2007; 18(Suppl 1):S149).
3. The weave of the mesh produces very small interstices which allow bacteria to enter and to hide from the host defenses designed to eliminate them. The bacteria can secrete an encasing slime (biofilm) which further serves to protect them from destruction by white blood cells and macrophages (Osterberg B. ActaChirScand1979; 145:431, Merritt K. J BiomatAppl 1991; 5:185, An Y. J Biomed Mater Res (ApplBiomat) 1998; 43:338).

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4. The large surface area promotes wicking of fluids and bacteria which provides a safe haven for bacteria which attach themselves to the mesh during the insertion process (Mahmoud W. J Biomat Sci Polymer Ed 1996; 7:751, Klinge U. J Biomed Mater Res 2002; 63:765, Vollebregt A. Int Urogyn J 2009; 20:1345).
5. The size of the mesh placed equates to a large surface area with many places for bacteria to hide while being protected from host defenses (Mahmoud W. J Biomat Sci Polymer Ed 1996; 7:751, Klinge U. J Biomed Mater Res 2002; 63:765, Vollebregt A. Int Urogyn J 2009; 20:1345).
6. Polypropylene is impure: There is no such thing as pure polypropylene. Polypropylene contains about 15 additional compounds which are leached from the polypropylene and are toxic to tissue which enhances the inflammatory reaction and the intensity of fibrosis (Sternschuss G. J Urol 2012; May 12 epub, Frostling H. Scand J Work Environ Health 1984; 10:163).
7. Prolene (polypropylene) was shown to be not inert in 1986 and again in 2003 with flaking and fissuring demonstrated by scanning electron microscopy which leads to degradation and release of toxic compounds. This enhances the inflammatory and fibrotic reactions (Coda A. Hernia 2003; 7:29, Jongebloed WL. Doc Ophthalmol 1986; 64:143–52).
8. With the loss of polypropylene due to degradation, the surface area is greatly increased thus providing greater areas for bacterial adherence and more elution of toxic compounds from the polypropylene and also the freed toxic polypropylene itself, all of which increases the inflammatory reaction and intensity of fibrosis (Jongebloed W. Doc Ophth 1986; 64:143, Sternschuss G. J Urol 2012; May 12 epub, Clave A. Int Urogyn J 2010; 21:261).
9. Complications from mesh placement for pelvic organ prolapse include among other adverse events: acute and chronic infection, tissue contraction due to mesh shrinkage, erosion of the mesh into adjacent structures, and dyspareunia [painful sexual intercourse]. Cosson, M., et al., Mechanical

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properties of synthetic implants used in the repair of prolapse and urinary incontinence in women: which is the ideal material? Int Urogynecol J Pelvic Floor Dysfunct, 2003. 14(3): p. 169-78; discussion 178. Jones, K.A., et al., Tensile properties of commonly used prolapse meshes. Int Urogynecol J Pelvic Floor Dysfunct, 2009. 20(7): p. 847-53. Margulies, R.U., et al., Complications requiring reoperation following vaginal mesh kit procedures for prolapse. Am J Obstet Gynecol, 2008. 199(6): p. 678 e1-4.

10. Erosion can be defined as the mesh wearing, or slowly grinding through the vaginal wall. This is a serious complication and moreover, there is evidence that meshes shrink in vivo leading to increased stiffness, pain and poor restoration of the normal properties of the vagina. Dora, C.D., et al., Time dependent variations in biomechanical properties of cadaveric fascia, porcine dermis, porcine small intestine submucosa, polypropylene mesh and autologous fascia in the rabbit model: implications for sling surgery. J Urol, 2004. 171(5): p. 1970-3.

11. Larger pores within polypropylene mesh materials, allowing macrophage and leukocyte migration, reduce infection. Birch C, Fynes MM. The role of synthetic and biological prosthesis in reconstructive pelvic floor surgery. Curr Opin Obstet Gynecol. 2002; 14:527–595. 22. Govier FE, Kobashi KC, Kozlowski PM, Kuznetsov DD, Begley SJ, McGonigle KF, et al. High complication rate identified in sacrocolpopexy patients attributed to silicone mesh. J Urol. 2005;65:1099–1103.

12. Defendant used Marlex® HGX-030-01 Polypropylene Homopolymer resin in its transvaginal mesh kits, both pelvic organ prolapse kits and sling systems. The Marlex® resin was manufactured by Phillips Sumika Polypropylene Company, ("Phillips") a joint venture between Chevron Phillips Chemical Company, LP, and Sumitomo Chemical.

13. Marlex HGX-030-01 resin is a polypropylene plastic that comes in the form of pellets. For several years, Phillips issued revised Material Safety Data Sheets ("MSDS") for Marlex polypropylene. Defendant was aware of the Marlex MSDS at all relevant times,

including when it manufactured and marketed its Products to the public, including Plaintiff and her physicians.

14. The Marlex MSDS expressly prohibits use of the material for permanent human implantation:

> MEDICAL APPLICATION CAUTION: DO NOT USE THIS CHEVRON PHILLIPS CHEMICAL MATERIAL IN MEDICAL APPLICATIONS INVOLVING PERMANENT IMPLANTATION IN THE HUMAN BODY OR PERMANENT CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES.
>
> DO NOT USE THIS CHEVRON PHILLIPS CHEMICAL COMPANY LP MATERIAL IN MEDICAL APPLICATIONS INVOLVING BRIEF OR TEMPORARY IMPLANTATION IN THE HUMAN BODY OR CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES UNLESS THE MATERIAL HAS BEEN PROVIDED DIRECTLY FROM CHEVRON PHILLIPS CHEMICAL COMPANY LP UNDER AN AGREEMENT WHICH EXPRESSLY ACKNOWLEDGES THE CONTEMPLATED USE.
>
> CHEVRON PHILLIPS CHEMICAL COMPANY LP MAKES NO REPRESENTATION, PROMISE, EXPRESS WARRANTY OR IMPLIED WARRANTY CONCERNING THE SUITABILITY OF THIS MATERIAL FOR USE IN IMPLANTATION IN THE HUMAN BODY OR IN CONTACT WITH INTERNAL BODY FLUIDS OR TISSUES.

15. When the Pelvic Mesh Products, including the Obtryx pelvic mesh product at issue in this case, are inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

16. On October 1, 2004, Phillips Sumika Polypropylene Company (PSPC) entered a one-year stand- alone indemnification/insurance agreement which waived the company's liability for Boston Scientific's decision to use the polypropylene material in medical applications. That agreement included the following language for Boston Scientific's use of the resin material in its transvaginal mesh products:

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> BEFORE USING ANY PSPC POLYPROPYLENE PRODUCT, BOSTON SCIENTIFIC IS ADVISED AND CAUTIONED TO MAKE ITS OWN DETERMINATION AND ASSESSMENT OF THE SAFETY AND SUITABILITY OF THE PSPC POLYPROPYLENE PRODUCT FOR USE BY, FOR OR ON BEHALF OF BOSTON SCIENTIFIC. IT IS THE ULTIMATE RESPONSIBILITY OF BOSTON SCIENTIFIC TO ENSURE THAT THE PSPC POLYPROPYLENE PRODUCT IS SUITED TO BOSTON SCIENTIFIC'S SPECIFIC APPLICATION.

17. The 2004 Indemnity Agreement placed the burden on Boston Scientific to conduct any and all necessary testing to ensure that the product it marketed with Marlex resin was safe for its intended use.

18. Subsequent to this 2004 indemnity agreement, in September of 2005, Phillips decided not to renew its contract with Boston Scientific because the resin was not intended for use in permanent implant devices. Per the terms of the 2004 contract between the two companies, Boston Scientific decided to exercise a right it held to make a "last-time" buyout before the contract was terminated. In 2005, BSC purchased 4,000 pounds of Marlex® HGX-030-01, the equivalent of a 10-year supply.

19. Synthetic materials like polypropylene, including that used by Defendant, are known to induce an acute inflammatory response, followed by chronic inflammatory response and foreign-body reaction. A chronic inflammatory response and heightened foreign body reaction have the potential to result in failure of the device to perform safely and effectively, with significant adverse consequences for the patient. Further, a prolonged inflammatory response exposes the polypropylene mesh to a continuous bath of oxidants that may cause in vivo degradation of the mesh.

20. The polypropylene MSDS specifies that polypropylene may react with strong oxidizing agents. Despite the known warnings and complications, Defendant utilized Marlex that had never been qualified by the supplier for permanent human implantation for a medical application that was disallowed according to the Material Safety Data Sheet (MSDS) in its manufacture of the Obtryx sling.

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21. The polypropylene mesh used by Defendant for its Pelvic Mesh Products also contracts as a result of the development of scar tissue exacerbated by the foreign body reaction. Polypropylene mesh is known to shrink by up to over 50% during healing. When the transvaginal mesh shrinks during the normal healing process, the arms of the mesh pull on its anchoring points in the pelvic sidewall muscles, tending to pull these anchoring points and the attached muscle toward the midline. In women with these transvaginal mesh implants, including Plaintiff herein, this pulling on the pelvic sidewall muscles causes pain at rest, during sexual intercourse, during defecation, and during normal daily activities like coughing, jumping and straining. This aggravated pulling will cause new or worsening pain to the women in whom the product is implanted. In addition, it is well established that nerves can become entrapped as a result of the chronic inflammatory response and fibrosis surrounding the mesh.

22. Defendant marketed the Pelvic Mesh Products, including the Obtryx pelvic mesh product, to the medical community and to patients as safe, effective, and reliable medical devices that can be implanted by safe, effective, and minimally invasive surgical techniques.

23. Defendant marketed and sold the Pelvic Mesh Products, including the Obtryx pelvic mesh product, through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies included, but are not limited to, aggressive marketing and the provision of valuable cash and non-cash benefits to healthcare providers. Defendant also utilized documents, patient brochures, and websites, offering exaggerated and misleading expectations as to the safety and utility of this product.

24. Contrary to the representations and marketing of Defendant, the Pelvic Mesh Products, including the Obtryx pelvic mesh product, have high failure, injury, and complication rates, fail to perform as intended, require frequent and often debilitating revision surgeries, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including Plaintiff. The defects stem from many issues, including:

a. the use of polypropylene material in the Pelvic Mesh Products and the immune reaction that results;

b. the design of the Pelvic Mesh Products to be inserted transvaginally into an area of the body with high levels of pathogens that adhere to the mesh, which can cause immune reactions and subsequent tissue breakdown;

c. the contraction or shrinkage of the mesh;

d. biomechanical issues with the design of the mesh that creates strong amounts of friction between the mesh and the underlying tissue that subsequently causes that tissue to degrade;

e. the use and design of anchors in the Pelvic Mesh Products that when placed correctly are likely to pass through and injure major nerve routes in the pelvic region;

f. degradation of the mesh itself over time which causes the internal tissue to degrade;

g. the welding of the mesh itself during production, which creates a toxic substance that contributes to the degradation of the mesh and host tissue; and

h. the design of the Obtryx's trocars used to facilitate passage through the obturator foramen requires tissue penetration in nerve-rich environments, which results frequently in the destruction of nerve endings.

25. Upon information and belief, Defendant has consistently underreported and withheld information about the propensity of its Pelvic Mesh Products, including the Obtryx pelvic mesh product, to fail and cause injury and complications, and have misrepresented the efficacy and safety of these products, through various means and media, actively and intentionally misleading the public.

26. Despite the chronic underreporting of adverse events associated with the Pelvic Mesh Products, enough complaints were recorded for the Food and Drug Administration ("FDA") to issue a public health notification regarding the dangers of these devices. On October 20, 2008, the FDA issued a Public Health Notification that described over a thousand (1,000) complaints (otherwise known as "adverse events") that had been reported over a three-year period relating to the Pelvic Mesh Products and other similar products. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, a review of the FDA's MAUDE database indicates that Defendant is one of the manufacturers of the products that are the subject of the notification.

27. On July 13, 2011, the FDA issued a Safety Communication entitled, "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse." Therein, the FDA advised that it had conducted an updated analysis of adverse events reported to the FDA and complications reported in the scientific literature and concluded

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that surgical mesh used in transvaginal repair of pelvic organ prolapse was an area of **"continuing serious concern"** (emphasis added). The FDA concluded that serious complications associated with surgical mesh for transvaginal repair of pelvic organ prolapse were "not rare." These serious complications include, but are not limited to, neuromuscular problems, vaginal scarring/shrinkage, and emotional problems. Many of the serious complications required medical and surgical treatment and hospitalization. The FDA concluded that it was not clear that transvaginal repair of pelvic organ prolapse and stress urinary incontinence with mesh-kits was more effective than traditional non-mesh repair of these conditions. The FDA conducted a systematic review of the published scientific literature from 1996 to 2011 and concluded that transvaginal pelvic organ prolapse repair with mesh "does not improve symptomatic results or quality of life over traditional non mesh repair." In the July 13, 2011, Safety Communication, the FDA concluded that "a mesh procedure may put the patient at risk for requiring additional surgery or for the development of new complications. Removal of the mesh due to mesh complications may involve multiple surgeries and significantly impair the patient's quality of life. Complete removal of mesh may not be possible." The information contained in the FDA's Public Health Notification of October 2008 and the FDA Safety Communication of July 13, 2011, was known or knowable to Defendant and was not disclosed in any manner.

28. In September 2011, the FDA acknowledged the need for additional data and noted in "Surgical Mesh For Treatment of Women with Pelvic Organ Prolapse and Stress Urinary Incontinence" that the literature and information developing on SUI repair with mesh "indicates that serious complications can occur…[and] a case can be made for additional premarket and/or post market studies to better address the risk/benefit of all mesh products used for SUI."

29. After the 2011 FDA notification that mesh complications from POP repairs were "not rare," a 2013 article was published that stated: "as outlined in the FDA notifications, patients should be forewarned that some transvaginal mesh complications are life altering and might not always be surgically correctable. Furthermore, that study noted that "the women who received both MUS and TM represented a complicated surgical group. Fifteen women (43%) required MUS takedown concurrently with prolapse mesh excision. Two-thirds of these women had associated chronic pelvic pain and vaginal pain, in addition to its urinary symptoms."

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30. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists (ACOG) and the American Urogynecologic Society (AUGS) also identified physical and mechanical changes to the mesh inside the body as a serious complication associated with vaginal mesh, stating: There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh…Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

31. Plaintiff's injuries, as will be more fully established in Discovery, are of the type reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion.

32. The FDA Safety Communication further indicated that the benefits of using transvaginal mesh products instead of other feasible alternatives did not outweigh the associated risks. Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk."

33. Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse" (the White Paper). In the White Paper, the FDA noted that the published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh."

34. The FDA White Paper further stated that, "these products are associated with serious adverse events…compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair."

35. In its White Paper, the FDA advises doctors to, inter alia, "[r]ecognize that in most cases, POP can be treated successfully without mesh thus avoiding the risk of mesh-related complications." The FDA concludes its White Paper by stating that it "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

36. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginal placed mesh in POP repair improves clinical outcomes any more than traditional POP repair

that does not use mesh, and it may expose patients to greater risk.

37. On April 16, 2019, the FDA ordered all manufacturers of surgical mesh intended for transvaginal repair of anterior compartment prolapse (cystocele) to stop selling and distributing its products immediately. In fact, the FDA has determined that the manufacturers, Boston Scientific and Coloplast specifically, have not demonstrated reasonable assurance of safety and effectiveness for these devices, which is the premarket standard that now applies to them since the agency reclassified them into class III (high risk) in 2016.[1]

38. Boston Scientific knew known about the Pelvic Mesh Products' risks and complications identified in the FDA Safety Communication, ACOG/AUGS Joint Committee Opinion, and the FDA Advisory that addressed the sales of transvaginal mesh implants for pelvic organ prolapse.

39. Defendant has further known the following:

a. that some of the predicate devices for the Pelvic Mesh Products had high failure and complication rates, resulting in the recall of some of these predicate devices;

b. that there were and are significant differences between the Pelvic Mesh Products and some or all of the predicate devices, rendering them unsuitable for designation as predicate devices;

c. that these significant differences render the disclosures to the FDA incomplete and misleading; and

d. that the Pelvic Mesh Product was and is causing numerous patients' severe injuries and complications.

40. Defendant suppressed this information and failed to accurately and completely disseminate or share this and other critical information with others, including Plaintiff. As a result, Defendant actively and intentionally misled and continues to mislead the public into believing that the Pelvic Mesh Products and the procedures for implantation were and are safe and effective.

[1] www.fda.gov/medical-devices/implants-and-prosthetics/urogynecologic-surgical-mesh-implants (last visited 10/14/2021).

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41. Defendant failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of the Pelvic Mesh Products. Defendant did not, and has not, adequately studied the extent of the risks associated with its Pelvic Mesh Products.

42. The Pelvic Mesh Products were at all times utilized and implanted in a manner foreseeable to Defendant, as it generated the directions for use, created the procedures for implanting the device, and trained the implanting physicians.

43. Defendant provided incomplete, insufficient, and misleading training and information to physicians to increase the number of physicians utilizing the Pelvic Mesh Products, and thus increase the sales of these products.

44. The injuries, conditions, and complications suffered by women who have been implanted with the Pelvic Mesh Products include, but are not limited to, mesh erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, acute and chronic nerve damage and pain, obturator nerve damage/neuralgia, pudendal nerve damage/neuralgia, pelvic floor damage, myofascial pain, chronic pelvic/extrapelvic pain, urinary and fecal incontinence, and prolapse of organs. In many cases, these women have been forced to undergo intensive medical treatment, including, but not limited to, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and surgeries to remove portions of the female genitalia, to locate and remove mesh, and to attempt to repair pelvic organs, tissue, and nerve damage.

45. The medical and scientific literature studying the effects of polypropylene pelvic mesh (like the material used in the Pelvic Mesh Products) have examined each of these injuries, conditions, and complications and determined that they are in fact casually related to the mesh itself and do not often implicate errors related to the implantation of the devices.

46. Defendant knew and had reason to know that the Pelvic Mesh Products could and would cause severe and grievous personal injury to the users of the Pelvic Mesh Products, and that they were inherently dangerous in a manner that exceeded any purported, inaccurate, or otherwise downplayed warnings.

47. At all relevant times herein, Defendant continued to promote the Pelvic Mesh Products as safe and effective even when no clinical trials had been done supporting long or short-term efficacy.

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Defective Design

48. The Obtryx is designed to be inserted into the obturator internus muscle, producing a foreseeable risk of acute and chronic myofascial pain as well as a foreseeable risk of (1) obturator neuralgia, by virtue of its passage into the obturator internus muscle, and (2) pudendal neuralgia, by virtue of its passage into the obturator internus muscle which runs alongside the pudendal nerve as the pudendal nerve passes through Alcock's Canal. Defendant failed to study or account for anatomic variations of the pudendal nerve when designing the device.

49. The Pelvic Mesh Products were designed to be permanently implanted into a woman's body yet the product changes after implantation; it contracts over time which can pull or compress nerves important for sexual function, mobility, bowel function, bladder function, and chronic pelvic and nerve pain (neuralgia). This contraction over time, which can pull, and also cause fibrosis of muscles, muscle spasms, adhesions between tissues, and inflammation which impair sexual function, impaired mobility, impaired bowel and bladder function, and chronic pelvic pain, neuralgia, among other mesh-related issues.

50. Moreover, despite claims that polypropylene mesh is inert, the scientific evidence shows that this material as implanted in Plaintiff is biologically incompatible with human tissue and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendant's Pelvic Mesh Products, including the Obtryx pelvic mesh product at issue herein. This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, causes chronic inflammation of the pelvic tissue, causes shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response and chronic pain, cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the polypropylene mesh.

51. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure,

physical properties, or appearance in the materials that are used in device construction."

52. Defendant's Pelvic Mesh Products, including the Obtryx pelvic mesh product at issue, were and are unreasonably susceptible to degradation and fragmentation inside the body, shrinkage or contraction inside the body, intense foreign body reaction, chronic inflammatory response, chronic wound healing, chronic infections in and around the mesh fibers, and nerve entrapment in the collagen scar formation. Defendant knew or should have known of these serious risks and should have, therefore, warned physicians and patients regarding these risks to the extent they were known or knowable.

53. To this day, the Obtryx pelvic mesh product continues to be marketed to the medical community and to patients as safe, effective, and reliable medical devices, implanted by safe, effective, and minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments and other competing products.

54. Defendant knew or should have known that its Pelvic Mesh Products, including the Obtryx pelvic mesh product at issue in this case, unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks. At the time Defendant began marketing the Obtryx, Defendant was aware that the Obtryx was associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011, safety communication.

55. Defendant omitted and downplayed the risks, dangers, defects, and disadvantages of its Pelvic Mesh Products, including the Obtryx pelvic mesh product at issue, and advertised, promoted, marketed, sold and distributed the its Pelvic Mesh Products, including the Obtryx pelvic mesh product at issue, as safe medical devices when Defendant knew or should have known that the Pelvic Mesh Products were not safe for its intended purposes, and that the products would cause, and did cause, serious medical problems, and in many patients, including Plaintiff, catastrophic injuries. Further, while some of the problems associated with the Pelvic Mesh Products, including the Obtryx pelvic mesh product, were made known to physicians, the magnitude and frequency of these problems were not disclosed and were hidden from physicians.

56. Contrary to Defendant's representations and marketing to the medical community and to the patients themselves, its Pelvic Mesh Products, including the Obtryx pelvic mesh product at issue, have high rates of failure, injury, and complications, fail to perform as intended,

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require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff, making them defective under the law.

57. Further, Defendant failed to design and establish a safe, effective procedure for removal of its Pelvic Mesh Products, including the Obtryx pelvic mesh products at issue, or to determine if a safe, effective procedure for removal of the Pelvic Mesh Products exists. Thus, in the event of a failure, injury, or complications, it is impossible to easily and safely remove the Pelvic Mesh Products.

58. Feasible, suitable, and safer alternative designs to Defendant's Obtryx pelvic mesh products, have existed at all times relevant and in reasonable probability would have prevented or significantly reduced the risk of Plaintiff's injuries without substantially impairing the products' utility. These safer alternative designs were economically and technologically feasible at the time the Pelvic Mesh Products left the control of Defendant by the application of existing or reasonably achievable scientific knowledge. Safer alternatives designs for the Obtryx included but were not limited to: the Burch Procedure colposuspension with delayed absorbable sutures; autologous fascia slings; an allograft sling using a product like Boston Scientific's Repliform® or other biological matrix; a sling with less polypropylene such as Ultrapro; a sling made with DynaMesh or other Polyvinylidene fluoride (PVDF) alternative, a retropubic sling, a retropubic mini-sling, such as the TFS device from TFS Surgical, a retropubic sling comprised of Dynamesh or other PVDF alternative, or a retropubic mini-sling comprised of DynaMesh or other PVDF alternative.

59. The specific nature of defects for Defendant's Obtryx pelvic mesh product at issue in this case include, but are not limited to, the following:

A. The use of polypropylene in the Pelvic Mesh Products and the adverse tissue reactions and host defense response that result from such material, causing adverse reactions and serious, permanent injuries including, but not limited to, painful recurrent erosions and associated intractable pain;

B. The design of the Obtryx to be inserted into and through an area of the body that is blood vessel rich, nerve dense, and bacteria laden leading to excessive blood loss and vascular damage, permanent nerve injury and associated chronic, intractable neuropathic pain, contaminated permanently-implanted mesh causing chronic

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infections, subclinical infections and biofilms, enhanced chronic inflammatory response, chronic wound healing with tissue destruction, as well as numerous other adverse reactions and serious and permanent injuries;

C. The use and design of a trocar and anchors in the Obtryx sling, which, when placed in the women, are likely to pass through contaminated spaces and that can injure major nerve routes in the pelvic region;

D. The procedure to place the Obtryx sling requires placing the anchors of the device through the obturator foramen that can injure major nerves that contribute to sexual function, contribute to mobility, and contribute to bowel and bladder function;

E. Biomechanical issues with the design of the Obtryx which results in a non-anatomic condition leading to contraction or shrinkage of the mesh inside the body, that in turn causes surrounding tissue to become eroded, inflamed, fibrotic and infected, resulting in serious and permanent injury;

F. The propensity of the mesh design characteristics of the Obtryx mesh for plastic deformation when subjected to tension both during implantation and once implanted inside the body which causes the mesh, or portions thereof, to be encapsulated in a rigid scar plate which leads to nerve entrapment, bacterial entrapment, tissue destruction, enhanced inflammatory and fibrotic response and chronic pain;

G. The propensity of the mesh used in the Obtryx mesh to become rigid and inflexible, causing it to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where the product is implanted, and causing discomfort and pain with normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

H. The propensity of the mesh used in the Obtryx for degradation or fragmentation over time, which causes an increased surface area that leads to enhanced chronic inflammatory and fibrotic reaction, causes a “barbed wire” or “saw blade” effect by the fragmented surface “sawing” through the tissue, leads to bacteria harboring in the fragmented, peeled and split fiber surface which in turn leads to chronic infections at the mesh surface, and results in continuing injury over time; and

I. The inability of surgeons to effectively treat many of these conditions due to the integration of the mesh into the pelvic tissue and thus the inability to safely remove

or excise the mesh once a complication occurs.

Failure to Warn/Inadequate Warnings & Instructions

60. At all relevant times herein, Defendant failed to provide sufficient warnings and instructions that would have put the Plaintiff, her treating physicians, and the public on notice of the dangers and adverse effects caused by implantation of the Pelvic Mesh Products.

61. The Obtryx is also defective due to Defendant's failure to adequately warn or instruct Plaintiff and/or her health care providers after the product left the manufacturer and before and after implantation of the Obtryx pelvic mesh product of subjects including, but not limited to, the following:

A. The Pelvic Mesh Products' propensities, including the Obtryx product, to contract, retract, and/or shrink inside the body;

B. The Pelvic Mesh Products' propensities, including the Obtryx product, for degradation, fragmentation and/or migration;

C. The Pelvic Mesh Products', including the Obtryx product, inelasticity preventing proper mating with the pelvic floor and vaginal region;

D. The frequency and manner of transvaginal mesh erosion or extrusion resulting from the Pelvic Mesh Products, including the Obtryx product;

E. The risk of chronic inflammation resulting from the Pelvic Mesh Products, including the Obtryx product;

F. The risk of chronic infections resulting from the Pelvic Mesh Products, including the Obtryx product;

G. The risk of permanent vaginal or pelvic scarring resulting from the Pelvic Mesh Products, including the Obtryx product;

H. The risk of de novo urinary dysfunction resulting from the Pelvic Mesh Products, including the Obtryx product;

I. The risk of de novo dyspareunia or painful sexual intercourse resulting from the Pelvic Mesh Products, including the Obtryx product;

J. The risk of recurrent, intractable pelvic/extrapelvic pain and other pain resulting from the Pelvic Mesh Products, including the Obtryx product;

K. The risk of obturator nerve irritation/obturator neuralgia resulting from the Pelvic Mesh Products, including the Obtryx product;

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L. The risk of pudendal nerve irritation/pudendal neuralgia resulting from the Pelvic Mesh Products, including the Obtryx product;

M. The need for corrective or revision surgery to adjust or remove the Pelvic Mesh Products, including the Obtryx product, which in some cases is not feasible nor possible;

N. The severity of complications that could arise as a result of implantation of the Pelvic Mesh Products, including the Obtryx product;

O. Treatment of stress urinary incontinence with Defendant's Obtryx Pelvic Mesh Product is no more effective than feasible, available and safer alternatives;

P. Treatment of stress urinary incontinence with Defendant's Obtryx Pelvic Mesh Product exposes patients to greater risk than feasible, available and safer alternatives;

Q. Treatment of stress urinary incontinence with the Obtryx Pelvic Mesh Product makes future surgical repair more difficult than feasible, available and safer alternatives;

R. Use of the Pelvic Mesh Products, including the Obtryx product, puts the patient at greater risk of requiring additional surgery than feasible, available and safer alternatives;

S. Removal of the Pelvic Mesh Products, including the Obtryx product, due to complications may involve multiple surgeries and may significantly impair the patient's quality of life;

T. Complete removal of the Pelvic Mesh Products, including the Obtryx product, may not be possible and may not result in complete resolution of the complications, including pain; and

U. The nature, magnitude, and frequency of the complications that could arise as a result of implantation of the Pelvic Mesh Products, including the Obtryx product.

V. The Pelvic Mesh Products' defects and hazards described herein;

62. Defendant underreported and continues to underreport information about the propensity of its Pelvic Mesh Products, including the Obtryx pelvic mesh product at issue, to fail and cause injury and complications and have made unfounded representations regarding the efficacy and safety of the Pelvic Mesh Products through various means and media.

63. Defendant underreported and continues to underreport information about the propensity of its Pelvic Mesh Products, including the Obtryx pelvic mesh product at issue, to

fail and to cause injury and complications and have made unfounded representations regarding the efficacy and safety of its Pelvic Mesh Products, including the Obtryx pelvic mesh product at issue, through various means and media.

64. Defendant failed to perform proper and adequate testing and research in order to determine and evaluate the nature, magnitude and frequency of the risks attendant to its Pelvic Mesh Products, including the Obtryx pelvic mesh product at issue.

65. The Obtryx pelvic mesh product at issue was at all times utilized and implanted in a manner intended and/or foreseeable to Defendant, as Defendant generated the instructions for use, created the procedures for implanting the devices, and trained the implanting physician.

66. Defendant knowingly provided incomplete and insufficient training and information to physicians regarding the use of its Pelvic Mesh Products, including the Obtryx pelvic mesh product at issue, and the aftercare of patients implanted with those Pelvic Mesh Products.

67. At all relevant times herein, Defendant continued to promote its products as safe and effective even when no clinical trials had been done supporting long-term or short-term efficacy or safety. In doing so, Defendant failed to disclose the known risks and failed to warn of known or scientifically knowable dangers and risks associated with its Pelvic Mesh Products, including the magnitude and frequency of these risks.

68. At all relevant times herein, Defendant failed to provide sufficient warnings and instructions that would have put Plaintiff, the medical community, Plaintiff's treating physicians, and the general public on notice of the dangers and adverse effects caused by implantation of the Defendant's Pelvic Mesh Products, including the Obtryx pelvic mesh product at issue.

69. Defendant's Pelvic Mesh Products, including the Obtryx pelvic mesh product at issue, as designed, manufactured, distributed, sold and/or supplied by Defendant, were defective as marketed due to inadequate warnings, instructions, labeling and/or inadequate testing in the presence of Defendant's knowledge of lack of safety.

70. The risk of serious injuries was known or should have been known to Defendant, but in spite of these risks, Defendant continued to market the Obtryx pelvic mesh product for transvaginal use to physicians and patients, including Plaintiff and Plaintiff's healthcare providers, without adequate warnings.

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Resulting Injury from Defendant's Pelvic Mesh Products

71. The injuries, conditions, and complications suffered by numerous women around the world who have been implanted with Defendant's Pelvic Mesh Products include, but are not limited to: erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, obturator nerve damage/neuralgia, pudendal nerve damage/neuralgia, pelvic floor damage, chronic pelvic/extrapelvic pain pain, emotional distress and mental anguish, and other debilitating complications. In addition, affected women, including Plaintiff, will need to be continuously monitored because of being implanted with Defendant's Pelvic Mesh Products.

72. In many of these cases, including that of the Plaintiff, women have had or will have to undergo extensive medical treatment, including, but not limited to, operations to locate and remove mesh, operations to attempt to repair pelvic organs, tissue, and nerve damage, the use of pain control and other medications, injections into various areas of the pelvis, spine, and the vagina, and operations to remove portions of the female genitalia. Removal of contracted, eroded and/or infected transvaginal mesh can require multiple surgical interventions for removal of mesh and results in scarring on fragile compromised pelvic tissue and muscles.

73. The medical and scientific literature studying the effects of pelvic mesh products, like that of the Obtryx pelvic mesh product implanted in Plaintiff, has examined each of these injuries, conditions, and complications, and has reported that they are causally related to the pelvic mesh products.

Plaintiff's Obtryx Implantation

74. Upon information and belief, Jeffrey D. Upton, M.D. recommended the Obtryx pelvic mesh product to Plaintiff as appropriate and safe for the treatment of her stress urinary incontinence. Consequently, Plaintiff consented to the implantation of the Obtryx pelvic mesh product.

75. On or about August 5, 2005, Plaintiff underwent surgery to address her stress urinary incontinence with Dr. Upton at Sierra Surgery and Imaging in Carson City, Nevada. During this surgery, she was implanted with a Boston Scientific Obtryx sling.

76. The Obtryx pelvic mesh product implanted in Plaintiff was in the same or substantially similar condition as it was when it left Defendant's possession, and in the condition

directed by and expected by Defendant.

77. Plaintiff and her physician foreseeably used and implanted the Obtryx pelvic mesh product properly and appropriately and did not misuse or alter these products in an unforeseeable manner.

78. Neither Plaintiff nor her healthcare providers were warned that the Obtryx pelvic mesh product was unreasonably dangerous or of the risks of the Pelvic Mesh Products, outlined herein, even when used exactly as intended by Defendant. To the contrary, Defendant promoted and sold the type of transvaginal mesh devices implanted in Plaintiff and thousands of women like Plaintiff, to healthcare providers as a safe alternative to other procedures that did not incorporate the Defendant's products.

79. On or about February 19, 2016, Plaintiff underwent a transvaginal sling revision procedure, performed by Seshadi Kasturi, M.D. at Fort Sutter Surgery Center in Sacramento, California, in order to attempt relief for Plaintiff's pelvic pain, extrapelvic pain, groin pain, leg pain, abdominal pain, urinary problems, nerve pain and dyspareunia caused by Defendant's Obtryx sling.

80. As a direct and proximate cause of having the Obtryx pelvic mesh device implanted in her, Plaintiff has experienced significant physical injuries and mental and physical pain and suffering, including pelvic pain, extrapelvic pain, groin pain, abdominal pain, dyspareunia, nerve pain, recurrence of incontinence, urinary problems, has undergone a revision/repair procedure and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages.

81. As a direct and proximate result of being surgically implanted with Defendant's unreasonably dangerous Obtryx pelvic mesh product, Plaintiff has suffered, and continues to suffer, debilitating injuries, including but not limited to the injuries listed above and, likely, nerve pain that may be permanent. In addition and in the alternative, Plaintiff suffered from pre-existing injuries/conditions which were aggravated, exacerbated, and/or accelerated by implantation of the Obtryx device. Plaintiff brings this suit for damages related to those injuries.

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DISCOVERY RULE AND TOLLING

82. Plaintiff realleges and incorporates by reference paragraphs 1 through 81 of this Complaint as if each were set forth fully and completely herein.

83. To the extent further pleading be necessary, Plaintiff asserts all applicable contractual[2], state statutory, and/or common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, class action tolling, delayed discovery, discovery rule, and fraudulent concealment.

84. Plaintiff could not have reasonably discovered her injuries and/or the occasion, manner and/or means by which Defendant's breach of duty occurred until within two years of the filing of this complaint. Further, Plaintiff did not and, exercising reasonable diligence, including consultation with medical professionals, could not discover the existence of her legal cause of action or the injuries caused by Defendant's breach of duty and/or defective products until within three years of the filing of this complaint.

85. Moreover, Defendant continues to deny that its products are defective or cause injuries such as those suffered by Plaintiff and Defendant continued to manufacture and sell the products at issue and/or related or predicate products. Any applicable statute of limitations has been tolled due to equitable tolling by the knowing and active concealment, affirmative misrepresentations, and denial of material facts known by Defendant when Defendant had a duty to disclose and/or by the application of the discovery rule. As a result of Defendant's fraudulent concealment, Plaintiff and her healthcare providers were unaware, and could not have known or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of Defendant.

86. At all relevant times, Defendant was in the business of developing, designing, licensing, distributing, selling, marketing, advertising, and delivering, and introducing into interstate commerce including, *inter alia*, within the United States and, specifically, within the State of Nevada, either directly or indirectly through third parties, subsidiaries or related entities, pelvic mesh products (the "Pelvic Mesh Products").

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[2] Plaintiff would represent that the time to file her complaint was tolled to July 28, 2022, pursuant to a tolling agreement between Plaintiff's previous counsel, The Flint Law Firm, and Defendant.

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VI. CLAIMS FOR RELIEF

COUNT I
NEGLIGENCE

87. Plaintiff incorporates each and every paragraph of this Complaint by reference asif fully stated herein and further states and alleges as follows.

88. At all times herein mentioned, Defendant was engaged in the business of researching, designing, selling, marketing, packaging and advertising the Obtryx product at issue in this case.

89. At all times relevant hereto, Defendant owed to Plaintiff and the public a duty to act reasonably and to exercise ordinary care with respect to the safe, legal, and proper design, formulation, testing, inspection, research, marketing, labeling, packaging, preparation for use, issuance of warnings with respect to use, promotion, advertising, sale, and safety monitoring of the Obtryx, and to adequately test and warn of the risk and dangers of the Obtryx, both before and after sale.

90. Additionally, Defendant owed to Plaintiff and the public a duty to provide accurate, reliable, and completely truthful information regarding the safety and any dangerous propensities of the Obtryx manufactured, used, distributed, and/or supplied by them and to provide accurate, reliable, and completely truthful information regarding the failure of the Obtryx to perform as intended or as an ordinary consumer would expect.

91. At all times relevant hereto, Defendant breached the aforementioned duties in that Defendant negligently and carelessly designed, formulated, tested, inspected, researched, marketed, labeled, packaged, prepared for use, promoted, and advertised the Obtryx, and failed to adequately test, monitor, and warn of the risk and dangers of the Obtryx, both before and after the product's sale, causing, directly and proximately, the injuries of Plaintiff through failure of the Obtryx to perform as intended or as an ordinary consumer would expect. Specifically, Defendant violated the duties of ordinary care and skill owed by Defendant to Plaintiff in the following particular respects:

a. Failing to conduct adequate and appropriate testing of its Pelvic Mesh Products such as the Obtryx to ensure they were safe for implantation in the female pelvis;

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b. Putting its Pelvic Mesh Products such as the Obtryx on the market without first conducting adequate testing to determine possible side effects;

c. Putting its Pelvic Mesh Products such as the Obtryx on the market without adequate testing of its dangers to humans;

d. Failing to recognize the significance of the medical literature, its own testing, and/or the testing of, and information regarding its Pelvic Mesh Products such as the Obtryx, when said literature/testing evidenced such products' potential harm to humans;

e. Failing to respond appropriately and promptly to the medical literature, its own testing, and/or the testing of, and information regarding its Pelvic Mesh Products such as the Obtryx, when said literature/testing evidenced such products' potential harm to humans;

f. Failing to promptly and adequately warn of the potential of its Pelvic Mesh Products such as the Obtryx to be harmful to humans;

g. Failing to promptly, adequately, and appropriately recommend testing and monitoring of the patients of its Pelvic Mesh Products, including patients implanted with the Obtryx product, in light of the knowledge that said Pelvic Mesh Products had the potential to be harmful to humans;

h. Failing to properly, appropriately, and adequately monitor the post-market performance of Defendant's Pelvic Mesh Products, including the Obtryx, as well as said products' effects on patients;

i. Concealing from the FDA, the National Institutes of Health, the general medical community and/or physicians, its full knowledge and experience regarding the potential that Defendant's Pelvic Mesh Products, including the Obtryx, could be harmful to humans;

j. Promoting, marketing, advertising and/or selling Defendant's Pelvic Mesh Products, including the Obtryx, for use on patients given its knowledge and experience of said Pelvic Mesh Products' potential harmful effects;

k. Failing to withdraw its Pelvic Mesh Products, including the Obtryx, from the market, restrict their use and/or adequately warn of said Pelvic Mesh Products' potential dangers, given its knowledge of the potential for harm to humans;

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l. Failing to fulfill the standard of care required of a reasonable, prudent, urogynecological medical device manufacturer engaged in the design, manufacturer, and marketing of its Pelvic Mesh Products, including the Obtryx;

m. Placing and/or permitting the placement of Defendant's Pelvic Mesh Products, including the Obtryx, into stream of commerce without warnings of the potential for said Pelvic Mesh Products to be harmful to humans and/or without properly warning of said Pelvic Mesh Products' dangerousness;

n. Failing to disclose to the medical community in a timely and appropriate manner, facts relative to the potential of Defendant's Pelvic Mesh Products, including the Obtryx, to be harmful to humans;

o. Failing to respond or react promptly and appropriately to reports of Defendant's Pelvic Mesh Products, including the Obtryx, causing harm to patients;

p. Disregarding the safety of users and consumers of the Obtryx and Defendant's other Pelvic Mesh Products, including Plaintiff, under the circumstances by failing to adequately warn of said Pelvic Mesh Products' potential harm to humans;

q. Disregarding the safety of users and consumers of the Obtryx and Defendant's other Pelvic Mesh Products, including Plaintiff, and/or her physicians and/or hospital, under the circumstances by failing to withdraw said Pelvic Mesh Products from the market and/or restricting their usage;

r. Disregarding publicity, government and/or industry studies, information, documentation, and recommendations, consumer complaints and reports and/or other information regarding the hazards of Defendant's Pelvic Mesh Products, including the Obtryx, and their potential harm to humans;

s. Failing to exercise reasonable care in informing physicians and/or hospitals using Defendant's Pelvic Mesh Products, including the Obtryx, about its knowledge regarding said Pelvic Mesh Products' potential harm to humans;

t. Failing to remove its Pelvic Mesh Products, including the Obtryx, from the stream of commerce;

u. Failing to test its Pelvic Mesh Products, including the Obtryx, properly and/or adequately so as to determine their safety for use;

v. Promoting its Pelvic Mesh Products, including the Obtryx, as safe and/or safer than other comparative methods/products;

w. Promoting its Pelvic Mesh Products, including the Obtryx, on websites aimed at creating user and consumer demand;

x. Failing to conduct and/or respond to post-marketing surveillance of complications and injuries resulting from its Pelvic Mesh Products, including the Obtryx;

y. Failing to use due care under the circumstances; and

z. Failing to monitor, analyze, and report to the FDA, medical community, its product users, and/or physicians and/or hospitals, adverse post-surgical outcomes stemming from the use of its Pelvic Mesh Products, including the Obtryx.

92. The acts of Defendant constitute violations of the duty of ordinary care and skill owed by Defendant to Plaintiff.

93. Plaintiff used and was implanted with Defendant's Obtryx in a manner that was reasonably foreseeable.

94. As the direct and proximate result of Defendant's negligent and/or reckless and/or wanton breaches of its aforementioned duties with respect to the Obtryx, Plaintiff suffered the injuries and damages alleged herein.

95. WHEREFORE, said Plaintiff prays for judgment against Defendant.

COUNT II

STRICT LIABILITY: DEFECTIVE DESIGN

96. Plaintiff incorporates each and every paragraph of this Complaint by reference as if fully stated herein and further states and alleges as follows.

97. At all relevant times, Defendant designed, researched, developed, manufactured, tested, labeled, advertised, promoted, marketed, sold and distributed, the Obtryx product which was implanted into Plaintiff.

98. Defendant's Obtryx product was expected to, and did, reach the intended consumers, handlers, and persons coming into contact with Defendant's Obtryx product without substantial change in the condition in which it was produced, manufactured, sold,distributed, labeled, and marketed by Defendant.

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99. At all relevant times, Defendant's Obtryx product was manufactured, designed, and labeled in an unsafe, defective, and inherently dangerous condition, which was dangerous foruse by the public, and, in particular, by Plaintiff.

100. Defendant's Obtryx product was defective in design and formulation in that, when it left Defendant's hands, the foreseeable risks exceeded the benefits allegedly associated with the design of the Obtryx product.

101. Defendant's Obtryx product was defective in design because, when it left the Defendant's hands, it was unreasonably dangerous and also was more dangerous than the ordinary consumer would expect.

102. At all relevant times, Defendant's Obtryx product was in a defective condition and unsafe, and Defendant knew, or should have known, that its Obtryx product was defective and unsafe, especially when used in the manner instructed and provided by Defendant.

103. Defendant knew, or should have known, at all relevant times, that the Obtryx product was in a defective condition, and was and is inherently dangerous and unsafe when used in the manner instructed and provided by Defendant.

104. At the time that the Obtryx product was implanted into Plaintiff, it was being used for its intended use in a manner normally intended, namely to treat pelvic organ prolapse.

105. Defendant had a duty to create a product, to wit, its Obtryx product, that was not unreasonably dangerous for its normal, common, intended use.

106. As the direct and proximate result of the Obtryx product's defective design, Plaintiff suffered the injuries and damages alleged herein.

107. By reason of the foregoing, Defendant is strictly liable in tort to Plaintiff.

COUNT III

STRICT LIABILITY: FAILURE TO WARN

108. Plaintiff incorporates each and every paragraph of this Complaint by reference as if fully stated herein and further states and alleges as follows.

109. Defendant researched, developed, designed, tested, manufactured, inspected,

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labeled, distributed, marketed, promoted, and/or sold and/or otherwise released its Pelvic Mesh Products, including the Obtryx product at issue, into the stream of commerce within the State of Nevada and elsewhere, and directly advertised and marketed within the State of Nevada and elsewhere, its Pelvic Mesh Products, including the Obtryx product at issue, to consumers or persons responsible for consumers, and, therefore, had a duty to warn of the risks associated withthe use its Pelvic Mesh Products.

110. Defendant's Pelvic Mesh Products, including the Obtryx product at issue, were under the exclusive control of Defendant and were not accompanied by adequate labeling and warnings regarding adverse side effects and complications associated with the use of its Pelvic Mesh Products, including the Obtryx product at issue, or by adequate warnings regarding the comparativeseverity, duration and extent of the risk of injuries associated with use of its Pelvic Mesh Products, including the Obtryx product at issue.

111. Defendant's promotion and advertising campaign for its Pelvic Mesh Products, including the Obtryx product at issue, did *not* advise either consumers or healthcare providers that its Pelvic Mesh Products, including the Obtryx product at issue, presented multiple and dangerous medical risks, including erosion of the vaginal wall and other tissues, infection, permanent and substantial physical deformity, and the loss of the ability to perform sexually.

112. Defendant failed to perform or otherwise facilitate adequate testing; such testing would have demonstrated that its Pelvic Mesh Products, including the Obtryx product at issue, posed serious and potentially life-threatening side effects and complications with respect to which full and proper warning accurately and fully reflecting the symptoms, scope and severity should have been made to healthcare providers, to the FDA, and to consumers, including Plaintiff.

113. Defendant's Obtryx product was defective due to inadequate post-marketing surveillance and warnings because Defendant knew, or should have known, the risks of serious side effects, including, but not limited to, erosion of the vaginal wall and other tissues, infection, permanent and substantial physical deformity, and the loss of the ability to perform sexually.

114. Defendant failed to timely and reasonably warn of material facts regarding the safety and efficacy of its Pelvic Mesh Products, including the Obtryx product at issue; no healthcare provider would have prescribed — and no consumer would have used — its Pelvic

Mesh Products, including the Obtryx product at issue, had the facts concerning the safety and efficacy of said Pelvic Mesh Products, been made known to such healthcare providers and consumers.

115. As a direct, foreseeable and proximate result of Defendant's foregoing conduct, Plaintiff has suffered and will continue to suffer serious and permanent physical and emotional injuries, has incurred medical expenses, has suffered and will continue to suffer economic loss, and has otherwise been physically, emotionally, and economically injured.

116. By reason of the foregoing, Defendant is strictly liable in tort to Plaintiff.

COUNT IV

NEVADA DECEPTIVE TRADE PRACTICES ACT VIOLATIONS

117. Plaintiff incorporates by reference each and every preceding paragraph as though fully set forth herein, and further alleges:

118. The acts of all Defendants described herein also constitute violations of Nevada's Deceptive Trade Practices Act, as codified in NRS Chapter 598, in that Defendants:

a. Knowingly made a false representation as to the characteristics, ingredients, uses, benefits, alterations or quantities of goods or services for sale or lease [NRS 598.0915(5)];

b. Represented that goods or services for sale or lease were of a particular standard, quality or grade, or that such goods were of a particular style or model, where they knew or should have known that they were of another standard, quality, grade, style or model [NRS 598.0915(7)];

c. Knowingly made other false representations in a transaction affecting Plaintiff Rader and others similarly-situated [NRS 598.0915(15)];

d. Failed to disclose a material fact in connection with the sale or lease of goods or services [NRS 598.0923(2)].

119. As a direct and proximate result of Defendants' violations of Nevada's Deceptive Trade Practices Act, Plaintiff has suffered serious and permanent injuries, including pain and suffering, loss of capacity for the enjoyment of life, continuous abdominal pain, stabbing vaginal pain, leg pain, pelvic pain, pain and difficulty with urination and bowel movements, pain with

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walking, a recurrence of incontinence, dyspareunia, and medical intervention for her pain, including the need for painful surgical revision of the mesh in February 2016, as well as the need for continuing and future medical care and treatment. She has incurred significant expenses for medical care and treatment and will continue to incur such expenses in the future.

VII. DAMAGES

120. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

General and Special Damages

121. As a direct and proximate result of having the Obtryx implanted in her, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury which includes or more likely than not may include, *inter alia,* any of the following: pelvic nerve damage and disorders, myalgia, recurrent urinary tract infections, chronic dyspareunia, bowel and bladder dysfunction, pelvic, leg, and anorectal pain. Plaintiff's injuries, as will be more fully established in discovery, are of the exact type reported in the FDA Safety Communication and in the ACOG/AUGS Joint Committee Opinion. In addition to the above and foregoing, Plaintiff has suffered permanent physical disfigurement, physical impairment, and financial or economic loss, including, but not limited to, obligations for past and future medical services and expenses, and/or lost income, and other damages.

122. The injuries suffered by Plaintiff were caused by the wrongful acts and omissions of Defendant.

Exemplary/Punitive Damages

123. At all times relevant herein, Defendant:

a. Knew that its Pelvic Mesh Products, including the Obtryx, were dangerous, ineffective, and caused significant, life-altering complications and side-effects;

b. Concealed the dangers and health risks from Plaintiff, physicians, hospitals, other medical providers, the FDA, its users and the public at large;

c. Made misrepresentations to Plaintiff, physicians, hospitals, other medical providers, its users and the public at large as to the safety and efficacy of its Pelvic Mesh Products, including the Obtryx; and

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d. With full knowledge of the health risks associated with its Pelvic Mesh Products, including the Obtryx, and without adequate warnings of the same, designed, marketed, promoted, developed, sold and/or distributed its Pelvic Mesh Products, including the Obtryx, for routine use.

124. Defendant, by and through its officers, directors, managing agents, authorized sales representatives, employees and/or other agents engaged in acts and/or omissions which were willfully malicious, fraudulent, wanton, and/or grossly reckless, and which reflected a conscious disregard of the rights or safety of others. As such, the conduct of Defendant warrants the imposition of exemplary damages under all applicable legal standards.

VIII. JURY DEMAND

125. Plaintiff hereby demands a jury trial on all claims so triable in this action.

IX. PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests that Defendant be served and made to appear before this Court, and after trial in this cause prays for relief against Defendant, as follows:

a. General damages according to proof and in an amount to fully compensate Plaintiff for all of her injuries and damages, both past and present;

b. Special damages according to proof and in an amount to fully compensate Plaintiff for all of her injuries and damages, both past and present, including but not limited to, past and future medical expenses, costs for past and future rehabilitation and/or home health care, lost income, permanent disability, including, permanent instability and loss of balance, and pain and suffering;

c. Punitive/exemplary damages;

d. All other damages as allowed by law;

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e. Such further relief as this Court deems necessary, just, and proper.

Dated: July 27, 2022

RESPECTFULLY SUBMITTED,

WETHERALL GROUP, LTD.

By */s/ Peter C. Wetherall*

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